



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 14, 2014

Cordis Corporation
Dr. Michelle Ragozzino Rodgers
Sr. Regulatory Affairs Specialist
6500 Paseo Padre Pkwy.
Fremont, CA 94555

Re: K140438

Trade/Device Name: Micro Guide Catheter ELITE
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: PDU
Dated: October 9, 2014
Received: October 10, 2014

Dear Dr. Rodgers,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address


<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Kenneth J. Cavanaugh -S
for
Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K140438

Device Name

Micro Guide Catheter ELITE

Indications for Use (Describe)

The Micro Guide Catheter ELITE accessory is to be used with the Frontrunner® CTO Catheter. The Frontrunner® CTO Catheter is intended to facilitate the intraluminal placement of conventional guide wires beyond stenotic lesions (including chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

I. SUBMITTER

Cordis Corporation, a Johnson & Johnson Company
6500 Paseo Padre Parkway
Fremont, CA 94555

Contact Person: Michelle Ragozzino Rodgers, Ph.D.
Tel: (510) 248-2450
Fax: (510) 248-2533

Date Prepared: October 9, 2014

II. DEVICE

Name of Device: Micro Guide Catheter ELITE
Common Name: Percutaneous catheter
Classification Name: Catheter for Crossing Total Occlusions (21 CFR §870.1250)
Regulatory Class: Class II
Product Code: PDU

III. PREDICATE DEVICE

Micro Guide Catheter XP, previously cleared under K082143
This predicate has not been the subject of a recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Micro Guide Catheter ELITE is a 6F sheath compatible catheter designed to navigate and place guidewires in the peripheral vasculature and to provide additional support for the Frontrunner® CTO Catheter. The Frontrunner® CTO Catheter is indicated to facilitate the intraluminal placement of conventional guidewires beyond the stenotic lesions (including chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention. The Micro Guide Catheter ELITE is a single lumen torqueable tube containing a PTFE inner liner that is surrounded by a stainless steel braid, which is further encompassed by a polymer jacket, and features a final external hydrophilic coating. The proximal end utilizes a molded hub with a luer fitting for flushing, with winged tabs designed to facilitate maneuvering and torquing in the vasculature, while the distal tip contains a radiopaque marker band for visibility under

fluoroscopy. The Micro Guide Catheter ELITE is available in various configurations and several lengths.

The Micro Guide Catheter ELITE is provided sterile (by EO) and is intended for single use only.

V. INDICATIONS FOR USE

The Micro Guide Catheter ELITE accessory is to be used with the Frontrunner® CTO Catheter. The Frontrunner® CTO Catheter is intended to facilitate the intraluminal placement of conventional guide wires beyond stenotic lesions (including chronic total occlusions) in the peripheral vasculature prior to further percutaneous intervention.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject Micro Guide Catheter ELITE is identical in intended use to the predicate Micro Guide Catheter XP. No change was made to the operating principle or control mechanism. At a high level, the subject and predicate devices are based on the following same technological elements:

- Catheter—Facilitates placement of and provides support to Frontrunner® XP CTO Catheter
- Use of marker bands and radiopaque materials for fluoroscopic visualization of catheter tip
- 6F Sheath compatibility
- Use of hydrophilic coating for distal lubricity to advance through lesion
- Use of a standard male luer fitting for flush port
- EO sterilized, single use device

The changes to the subject device relative to the predicate are limited to minor modifications to the catheter shaft and tip and an improved packaging design. The following technological differences exist between the subject and the predicate devices:

- Modified shaft
- Distal tip shape
- Packaging size reduction and associated packaging material change

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

Biocompatibility Testing

Biocompatibility evaluation for the Micro Guide Catheter ELITE (subject device) leveraged the existing biocompatibility test data generated for the Micro Guide Catheter XP (predicate device). Supplemental biocompatibility testing to support the Micro Guide Catheter ELITE was performed on finished and sterilized catheters in compliance with U.S. Food and Drug Administration Good Laboratory Practice (GLP) regulations set forth in 21 CFR Part 58 and per ISO 10993-1:2009/Cor 1:2010 Biological evaluation of medical devices - Part 1. Supplemental Biocompatibility testing included the following tests:

- In vitro Cytotoxicity – MEM Elution
- In vitro Hemolysis - ASTM Extract & Direct Contact
- USP <661> Containers – Plastics, Physicochemical Tests

Extraction testing was also conducted on the Micro Guide Catheter ELITE.

Device Dimensional and Functional Testing

- Dimensional
- Tensile
- Leak
- Coating integrity
- Lubricity
- Stiffness and pushability
- Kink
- Torque strength and torque transmission
- Corrosion resistance
- Particulate
- Simulated use

Packaging and Sterilization

- Bioburden
- EO residuals
- Bacterial Endotoxin

Animal Study

Cordis conducted a GLP animal study to evaluate the performance of Micro Guide Catheter Elite under simulated conditions in a porcine model. Two animals were utilized for the acute evaluations in the peripheral vasculature. Four devices (2 test articles and 2 control articles) were evaluated in each animal and scored for radiopacity and the ability to rotate, advance and retract the devices. No procedure-related complications or deaths were reported. Evaluation arteries were grossly evaluated *in situ*, and following excision, they were longitudinally cut and evaluated for signs of damage or trauma. There was no evidence of tissue damage or perforation. This study demonstrated that the angled tip and added stiffness of the Micro Guide Catheter ELITE relative to the predicate device does not increase the risk of vessel damage or perforation.

VIII. CONCLUSIONS

The subject Micro Guide Catheter ELITE is the same in basic design and identical intended use as the legally marketed predicate, Micro Guide Catheter XP. The minor modifications made to the catheter shaft and tip and improved packaging design for Micro Guide Catheter ELITE product family do not alter the fundamental scientific technology of the device, the device's operating principles, mechanism of action, or the indication for the use of device. The design modifications made to the Micro Guide Catheter ELITE were verified and validated through a series of tests ensuring that the subject catheter meets the specifications and that the performance and functionality are substantially equivalent to the predicate device. The Micro Guide Catheter ELITE continues to meet all previous performance specifications, and none of the critical clinical performance parameters have changed. The modifications do not raise new questions of safety and effectiveness. Micro Guide Catheter ELITE can be used according to its intended use and in an equivalent manner to the predicate device.